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Pesticide Fact Sheet Number 139
Ethylenethiourea (ETU)

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This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

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EPA

Pesticide Fact Sheet

Name of Chemical: Ethylenethiourea (ETU)
Reason for Issuance: Initiation of Special Review
Date Issued: June 1987
Fact Sheet Number: 139

DESCRIPTION OF CHEMICAL:

Generic Name: NA

Common Name: Ethylenethiourea

Trade Names: NA

Chemical Abstracts Service (CAS) Number: 96-45-7

Year of Initial Registration: NA

Pesticide Type: Contaminant, degradation product, and metabolite of the EBDC pesticides.

U.S. and Foreign Producers: The principal producers of various of the EBDC pesticides include FMC Corporation, Pennwalt Corporation, and Rohm & Haas Company.

USE PATTERNS AND FORMULATIONS:

ETU is a contaminant, metabolite, and degradation product of the family of pesticides known as the EBDCs. There are five such pesticides currently registered: mancozeb, maneb, metiram, nabam, and zineb. All registrations of amobam products are now cancelled. In their agricultural uses, the EBDC pesticides are broad spectrum fungicides used to prevent crop damage by fungi and to protect harvested crops from deterioration. Some EBDC pesticides products are also used as industrial biocides in some applications.

Although these pesticides are used on a wide variety of crops, the principal crops on which they are used are apples, potatoes, and tomatoes. All types of formulation types are registered. Application is done by various methods, including airblast, ground boom, and sprinkler irrigation.

SCIENCE FINDINGS

Summary Science Statement: ETU has been classified by the Agency as a Group B2 oncogen (probable human carcinogen). ETU has induced an increased incidence of thyroid tumors in rats, and liver tumors in mice. In addition, ETU has been shown to be a teratogen in studies with rats and hamsters, and has shown thyroid effects in rat feeding studies.

Toxicology Characteristics

Subchronic Toxicity:

Oral (rats): NOEL for thyroid effects (Sprague-Dawley rats) - 5 ppm (0.25 mg/kg/day) (Freudenthal, 1977).

Oral (mouse): NOEL for liver effects - 10 ppm

NOEL for thyroid effects - 10 ppm (1.72 mg/kg/day, males; 2.38 mg/kg/day, female) (O'Hara & DiDonata, 1985).

Oral (monkey): NOEL for thyroid effects - < 50 ppm.

NOEL not determined for thyroid effects in the dog.

Chronic Toxicity:

Chronic Toxicity: No chronic NOEL determined for thyroid effects in the rat. Study required in Sprague-Dawley rats.

Oncogenicity: Potency estimate of 0.1428 mg/kg/day based on liver tumors in mice (Innes 1969).

Produced thyroid tumors in rats (Ulland 1972; Graham 1975).

Teratology: Teratogenic effects: NOEL (rats) - 5 mg/kg (Khera 1973). The dose resulting in abnormalities such as hydrocephalus in the hamster was 27 times that resulting in hydrocephalus in the rat.

Reproduction: Study required.

Mutagenicity: Mixed results - weakly genotoxic.

Tolerance Assessment: Tolerances have been set for maneb and zineb at 40 CFR 180.110 and 40 CFR 180.115, respectively. Tolerances for mancozeb, expressed as zinc ethylene bisdithiocarbamate, have been established for raw agricultural commodities at 40 CFR 180.176, for meat byproducts at 40 CFR 180.319, and in processed food and feed at 21 CFR 193.460 and 21 CFR 561.410, respectively.

SUMMARY OF REGULATORY POSITION & RATIONALE

The Agency is initiating a Special Review of the EBDC pesticides because of concern about the oncogenic risk to consumers from dietary exposure to ETU from foods treated with these pesticides, and the risks of teratogenicity and adverse thyroid effects to applicators and mixer/loaders from exposure to ETU. ETU is present as part of the residue of the EBDC pesticides on treated agricultural commodities. In addition, a portion of the EBDC pesticide residues convert into ETU in the body after ingestion. The Agency estimates that the lifetime dietary oncogenic risk to consumers from these two sources of exposure to ETU is 2.2×10^{-5}. This estimate is based on exposure to ETU from the residues of only one of the EBDC pesticides. Consequently, the overall dietary risk may be higher.

Applicators and mixer/loaders are exposed to ETU during application and mixing and loading of the EBDC pesticides. Because ETU is a contaminant, degradation product, and metabolite of these pesticides, it is present in tank mixes and in the formulations of the EBDC pesticides.

The Agency calculated margins of safety for teratogenic and thyroid effects from exposure to ETU in mancozeb, one of the EBDC pesticides. Several margins of safety were below the threshold of concern. (A safety factor of 100 is used to measure the acceptable margin between actual exposure and the levels at which chronic effects may occur. A margin of safety for chronic effects of less than 100 is unacceptable). For example, airblast applicators applying mancozeb to apples had margins of safety for exposure to ETU of 87 for teratogenic effects, and 11 for thyroid effects. Ground boom applicators applying mancozeb to potatoes, onions and tomatoes had margins of safety for exposure to ETU of less than 100 for thyroid effects. The Agency is not initiating a Special Review on oncogenic risks to applicators and mixer/loaders because the relative risks and the number of persons potentially exposed are low.

This elevated level of potential risk warrants a careful examination during the Special Review process of the risks and benefits of using the EBDC pesticides, and a determination whether such uses should be cancelled or otherwise regulated.

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